



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

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ADVISORY

COMPOUNDING PHARMACIES AND PHARMACISTS

The Board of Registration in Pharmacy reminds pharmacies and pharmacists who engage in compounding in the Commonwealth that Board Regulations (247 CMR) require that all actions be performed in accordance with United States Pharmacopeia (USP) Standards. 247 CMR 9.01(3). USP<795> addresses the practice for Non-Sterile Compounding and USP Standard <797> addresses the practice for Sterile Compounding Preparations

Massachusetts Pharmacies and Pharmacists are also reminded that Massachusetts General Law Chapter 94C, section 21 and Department of Public Health regulations (105 CMR 721.000) require that pharmacies and pharmacists dispense medications pursuant to a valid prescription from an authorized practitioner for a specific patient. This prescription must be valid as defined under Massachusetts statutes and regulations, not under the rules governing prescriptions in the recipient state.

Board licensees are advised to review USP standards and Board regulations 247 CMR 1.00 – 16.00 to assure that pharmacy practice is conducted in accordance with state and federal laws and regulations, as required by Massachusetts General Law Chapter 112, section 61 and Board regulation 247 CMR 9.01(1).

The Board advises that all compounding pharmacies and pharmacists should obtain and complete the respective USP Gap Analysis Tool(s) (®International Journal of Pharmaceutical Compounding), provided below, to determine preliminary compliance with the above-referenced USP standards.

Right-click → Open Hyperlink
Gap Analysis Tool - USP <795>
Gap Analysis Tool - USP <797>

The Board appreciates your prompt attention to this important advisory.